

## HOW TO LIMIT THE USE OF SERUM IN VIRAL PROCESSES: A GIBCO PERSPECTIVE

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Vaccine manufacturing targeting animal and human prophylaxis has been relying heavily on the use of sera to reach adequate titers in mammalian cell culture processes. Safety concerns, lack of process robustness, costs of qualification, supply and storage are some of the main challenges faced while using sera. Taking into account these drawbacks, sera has remained one of the principal raw materials in vaccine manufacturing, but with limited supply worldwide and increased demands, notably from the cell therapy industry, sera's poor economic predictability might become a major issue on cost of good models required for vaccine viability. Using Gibco's expertise in designing and manufacturing cell culture media for the past 55 years, we identified 4 approaches to limit the use of serum in viral processes. The first strategy to require limited process rework is by reducing the amount of serum in vaccine manufacturing through use of enriched basal media and/or bovine serum albumin as a substitute. The second option is to identify which step of the manufacturing process actually requires serum supplementation. Indeed, while cell growth in adherent conditions may require sera for expansion, the production phase after infection can sometimes eliminate use of FBS or BSA supplementation, thus simplifying processes and compliance to regulatory guidelines. The third approach, providing virus production is not adherence-dependent, is to adapt the adherent cell line to suspension culture, hence removing the need to provide attachment factors present in sera. Finally, when available, a completely controlled process can be developed using cells adapted to CD media (chemically-defined and protein-free). The Gibco perspective on vaccine technology is to streamline workflows while providing media capabilities to support vaccine manufacturers at large scale. This work will demonstrate that implementing a well-designed strategy to reduce or remove sera from current processes is an effective way to achieve a more robust and scalable viral process.